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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,250	02/28/2002	Paul D. Rubin	4821-469	4257

20582 7590 08/08/2003
PENNIE & EDMONDS LLP
1667 K STREET NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/08/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,250

Applicant(s)

RUBIN, PAUL D.

Examiner

Mina Haghighatian

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-49 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 17-29 and 42-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-16 and 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendments filed 05/14/03 were entered. Claims 31-36, 38 and 40 have been amended. No claims were cancelled and no new claims were added. (Note: Remarks indicates an intended amendment for claim 30, which was not included.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-16 and 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoh (5,120,758) in view of Woosley et al (6,124,320).

Satoh teaches compounds useful as selective lipxygenase inhibitors, methods of their preparation and methods of treating diseases such as allergic rhinitis using such compounds, alone or in combination with other active agents (col. 1, lines 8-22). Therapeutic agents suitable for combination with the lipxygenase inhibitors include leukotriene receptor antagonists such as ICI-204219, and antihistamines such as astemizole (col. 13, lines 13-63). The compositions disclosed by Satoh may be administered in any suitable form such as oral (col. 12, lines 31-39). Satoh lacks specific disclosure on norastemizole.

Woosley teaching methods for treating allergic disorders using norastemizole, states that "it has been discovered that these pharmaceutical compositions containing metabolic derivatives of astemizole are useful in treating allergic disorders and such other conditions...including but not limited to allergic rhinitis....while avoiding the above-described adverse effects associated with the administration of astemizole" (col. 3, lines 7-31). Woosley discloses that suitable metabolic derivatives are compounds including norastemizole (col. 3, lines 61-64). Also disclosed is that norastemizole may be combined with other therapeutically active compounds in an amount effective in treating allergic disorders (col. 3, lines 39-45).

Woosley discloses that any suitable route of administration may be employed for providing the patient with an effective dosage of the metabolic derivatives of astemizole. For example oral, parenteral or transdermal. Dosage forms include tablets, solutions and the like (col. 7, lines 16-22). The oral administration may be presented as discrete units such as capsules, cachets, tablets or aerosol sprays (col. 8, lines 12-17).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the formulations and methods of treating allergic rhinitis as taught by Satoh with the formulations and methods of treating allergic disorders such as allergic rhinitis of Woosley because Woosley is clearly disclosing the disadvantages of using astemizole and teaches that norastemizole, a metabolite of astemizole, is a suitable replacement and with the reasonable expectations of providing

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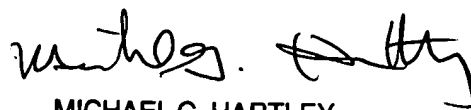
patients with a safe and effective formulation avoiding the undesirable side effects of astemizole.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
August 6, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER